Remarks

Claims 39-62 are pending in the subject application. Favorable consideration of the pending claims in view of the remarks presented herein is earnestly solicited.

The present invention advantageously provides a ventilation system having the ability to automatically, without clinician input, recommend ventilator control settings.

Claims 39-62 have been rejected under 35 U.S.C. §102(b) as being anticipated by Biondi *et al.* (U.S. Patent No. 6,158,432). The applicants respectfully traverse this grounds of rejection because the Biondi *et al.* reference does not teach or suggest the applicants' unique system for ventilation monitoring and control. Specifically, Biondi *et al.* does not disclose a system that recommends a ventilator control setting based on the evaluation by an intelligence system of at least one output signal.

The Biondi *et al.* system requires the clinician to select specific ventilator control settings. The Biondi *et al.* system then monitors the performance of the system and, based on simulator algorithms, adjusts the mechanics of the system to effect the directions that were selected by the clinician. The Biondi *et al.* system does not, and cannot, recommend appropriate settings to best facilitate patient care. Rather, the Biondi *et al.* system simply tries to carry out the operator's instructions. It is important to recognize that, when the current applicants refer to "ventilation control settings" they are referring to the settings that, when using the Biondi *et al.* system, must be entered by a clinician.

In rejecting the current applicants' claim 39 as being anticipated, the outstanding Office Action cites column 5, lines 30-42 of the Biondi *et al.* patent. The entire text cited by the Office Action is reproduced below. Please note that, in the cited passage, there is no disclosure, or even a suggestion, of recommending a ventilator control setting based on the evaluation by an intelligence system of at least one output signal.

> One feature of the ventilator control system **10** is that it can be configured to provide an assisted phase of a breath to the patient **20**. As noted previously, the accumulated volume of gas inhaled by the patient as a result of his spontaneous respiratory muscle activity can be monitored. To accomplish this, the sensor monitoring system **19** measures the flow of gas inhaled by the patient **20** at the beginning of the inspiration phase of the breath and integrates the flow to provide the

> measured volume. The embedded controller **14** compares the measured volume to a trigger volume set by the clinician **16**, and adjusts the plurality of controls within the pneumatic system **41** when the measured accumulated volume exceeds the trigger volume to provide an assisted phase of a breath. The embedded controller **14** also may adjust the trigger volume dynamically according to measured patient flow and pressure signals indicating the phase of the respiratory cycle. In particular, the embedded controller **14** may increase the trigger volume set by the clinician **16** during periods of the breath where increasing the pressure at the airway of the patient **20** may be induced by changes in the pneumatic system **41**, and not by spontaneous efforts of the patient.

The applicants respectfully submit that the cited passage actually illustrates important distinctions between the applicants' invention and the Biondi *et al.* system. Please note, for example, the reference to input provided by the clinician (fourth sentence). Please also note the absence of any indication that the ventilator control settings are adjusted (from what is set by the clinician) by an intelligence system based on an evaluation of the output. Rather, the simulator disclosed by Biondi *et al.* applies predetermined data structures with predetermined computational instructions to monitor patient ventilation (see for example, col. 13, line 57 through col. 14, line 62).

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

> Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman [v. Kimberly-Clarke*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

In *Dewey & Almy Chem. Co. v. Mimex Co.*, Judge Learned Hand wrote:

> No doctrine of the patent law is better established than that a prior patent . . . to be an anticipation must bear within its four corners adequate directions for the practice [of the subsequent invention] . . . if the earlier disclosure offers no more than a starting point . . . if it does not inform the art without more how to practice the new invention, it has not correspondingly enriched the store of common knowledge, and it is not an anticipation. 124 F.2d 986, 990; 52 USPQ 138 (2nd Cir. 1942).

The current applicants respectfully submit that Biondi *et al.* do not disclose the currently-claimed method and system wherein an intelligence system evaluates output signals and ventilator parameter signals to recommend ventilator control settings. Because Biondi *et al.* do not disclose such a system, the applicants' claims cannot be said to be anticipated by Biondi *et al.*

At page 2, Section 3, the outstanding Office Action characterizes certain recitations in the applicants' claims as "recitations of intended use." Please note that, with regard to method claims (such as the applicants' claims 39-50), recitations of intended use are, of course, critical distinctions upon which patentability may be based. Furthermore, the applicants respectfully submit that the claim limitations to which the Office Action refers are actually functional attributes of the claimed system. These functional attributes must have corresponding structures to perform the stated functions. The exact form of the structure is not critical to the invention; however the ability to perform the function is critical.

It is of course well established in the Patent Law that the Patent Office must recognize, and give patentable weight to, functional limitations. See, *e.g.*, *In re Land*, 151 U.S.P.Q. 621 (C.C.P.A. 1966) in which the court held that portions of a disputed claim were functional, but nevertheless held the claim patentable over the prior art in view of the functional limitations. The Patent Office must afford patentable weight to functional limitations even if the functional limitations are the only limitations that are nonobvious over the prior art. *In re Mills*, 16 U.S.P.Q 2d 1430 (Fed. Cir. 1990). *See also In re Atwood*, 148 U.S.P.Q. 203, 210 (C.C.P.A. 1966) ("[w]e have here a combination claim and the limitations ignored by the board as use limitations we think are functional expressions which must be given weight"); *In re Mills*, 16 U.S.P.Q. 2d 1430 (Fed. Cir. 1990); *In re Zurko*, 111 F.3d 887, 42 U.S.P.Q 2d 1476 (Fed. Cir.), *reh'g en banc granted*, 116 F.3d 874 (Fed. Cir. 1997). In addition,

the Manual of Patent Examining Procedure ("M.P.E.P.") expressly authorizes the use of functional language and specifically acknowledges that "[a] functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it conveys to a person of ordinary skill in the pertinent art in the context in which it is used." M.P.E.P. §2173.05(g) (8th Ed. 2001).

The distinctions between the current invention and the Biondi *et al.* system are not trivial. In fact, it is precisely the differences between the current invention and Biondi *et al.* that make the current invention particularly advantageous. The Biondi *et al.* system only uses rigid algorithms to try to control the ventilator in order to effect settings entered by the operator. Thus, the care of the patient still depends entirely on judgments made by the operator. In contrast, the subject invention provides a system whereby a multiplicity of variables can be monitored in order to assess the need of a particular patient. These variables, which can include various measures of the patient's physiological response to the ventilator can then be used to achieve the appropriate therapeutic goal. By carefully monitoring the patient in this way, it is now possible to improve and expedite recovery. This is, of course, a tremendous benefit to the patient, the caregiver and the hospital. Such an advantageous system is neither disclosed nor suggested by Biondi *et al.* Accordingly, the applicants respectfully request reconsideration and withdrawal of the prior art rejection based on Biondi *et al.*

In view of the foregoing remarks and amendment, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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